UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

JEFFREY JOSEPH MAYNARD,

Plaintiff,

v. Case No. 12-C-0939

ABBOTT LABORATORIES,

Defendant.

DECISION AND ORDER DENYING RULE 12(b)(6) MOTION TO DISMISS

Plaintiff Jeffrey Joseph Maynard brought this *pro se* failure-to-warn action, alleging he suffered neurological damage from using Humira, a prescription drug manufactured by Defendant Abbott Laboratories. Plaintiff took Humira over the course of several years to treat rheumatoid arthritis, but stopped using the drug after he began experiencing symptoms of vision loss, optic neuritis, and multiple sclerosis. Defendant filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), arguing that plaintiff's complaint should be dismissed for failure to state a claim upon which relief can be granted because his failure-to-warn claim is directly contradicted by the FDA-approved pharmaceutical warning label. Defendant argues that Humira's label has at all times specifically warned of the potential association between use of Humira and neurological side effects including development of a demyelinating disease such as multiple sclerosis or vision problems. For the reasons that follow, defendant's motion will be denied.

BACKGROUND

Plaintiff began taking Humira to treat rheumatoid arthritis in October 2003. Humira is a TNF blocker generally prescribed for people with moderate to severe rheumatoid arthritis to reduce symptoms such as pain and swollen joints and to prevent further damage to bones and joints. (Poland Decl., Ex. 1 at 23, ECF No. 9-1.) The Federal Drug Administration (FDA) initially approved Humira in December 2002.

Plaintiff took Humira "on a continuous basis" between 2003 and 2009. (Compl. 5.) On September 16, 2009, plaintiff began experiencing extreme and sudden vision loss in his left eye. (Compl. 5.) He had difficulty with coordination and with keeping his balance while walking. (Compl. 6.) After several examinations and tests, doctors determined he was suffering from demyelination disease resulting from his Humira use, and he exhibited symptoms of optic neuritis and multiple sclerosis. (Compl. 5-6.) After plaintiff was taken off the drug, his symptoms did not progress, but he has not regained vision in his left eye. (Compl. 6-7.) He alleges that while similar brands of TNF blocking drugs warned of optic nerve damage and demyelinating disease, Humira's label downplayed or omitted any mention of the severity of these neurological risks. (Compl. 6.) Plaintiff contends that the warnings included in the Humira label were inadequate. Under "WARNINGS" the October 2003 Humira label states:

> **Neurologic Events**
>
> Use of TNF blocking agents, including HUMIRA, has been associated with rare cases of exacerbation of clinical symptoms and/or radiographic evidence of demyelinating disease. Prescribers should exercise caution in considering the use of HUMIRA in patients with preexisting or recent-onset central nervous system demyelinating disorders.

(Poland Decl., Ex. 1 at 13, ECF No. 9-1.) In 2005, this warning was updated to state that in addition to being associated with rare cases of exacerbation of clinical symptoms and/or radiographic

evidence of demyelinating disease, use of Humira has also been associated with rare cases of new onset of such symptoms. (Poland Decl., Ex. 5 at 12-13, ECF No. 20-1.)

Under "ADVERSE REACTIONS" the label states that the most serious adverse reactions include "neurologic events" and refers to the neurologic events explained in the warnings section. (Poland Decl., Ex. 1. at 16, ECF No. 9-1.) Under "Other Adverse Reactions," the label lists multiple sclerosis and cataracts among the "infrequent serious adverse events occurring at an incidence of less than 5% in patients treated with HUMIRA." (Poland Decl., Ex. 1. at 20, ECF No. 9-1.)

Likewise, the Humira patient insert warns that patients should tell their doctor before starting to take Humira if they have experienced "any numbness or tingling or have or have ever had a disease that affects [the] nervous system like multiple sclerosis." It also states:

> Any medicine can have side effects. Like all medicines that affect your immune system, HUMIRA can cause serious side effects. The possible serious side effects include:
>
> * * *
>
> Nervous system diseases: There have been rare cases of disorders that affect the nervous system of people taking HUMIRA or other TNF blockers. Signs that you could be experiencing a problem affecting your nervous system include: numbness or tingling, problems with your vision, weakness in your legs and dizziness.

(Poland Decl., Ex. 1 at 24, ECF No. 9-1.)

Plaintiff alleges that the warnings provided were not adequate and therefore prevented him from making a well-informed decision about whether to take the drug and for how long. Plaintiff alleges that the label fails to warn about the "very serious potential side effects" of taking Humira, including deterioration of the optic nerves. (Compl. 6.) Had he known the full extent of the possible side effects, he could have made a decision to stop taking Humira sooner, and his injuries

would have been less serious. (Compl. 6-7.) He alleges that his vision problems have caused numerous other injuries, including balance problems, headaches, and dizziness. He also suffered a compound fracture, acute renal failure, and a concussion after falling due to his vision loss. (Compl. 6.) He also states that he will continue to require ongoing medical attention for his injuries resulting from his Humira use. Plaintiff contends that defendant knew or should have known that Humira posed risks to consumers but continued to manufacture and market the drug without adequately disclosing the alleged dangers it posed.

LEGAL STANDARD

Dismissal under Rule 12(b)(6) is proper "when the allegations in a complaint, however true, could not raise a claim of entitlement to relief." *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 558 (2007). To state a claim, a complaint must contain sufficient factual matter "that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). "[T]he plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). To survive dismissal, a plaintiff "must plead some facts that suggest a right to relief that is beyond the 'speculative level.'" *Atkins v. City of Chicago,* 631 F.3d 823, 832 (7th Cir. 2011) (quoting *In re marchFIRST Inc.,* 589 F.3d 901, 905 (7th Cir. 2009)). In considering a motion to dismiss, the court construes the allegations in the complaint in the light most favorable to the plaintiff, accepts all well-pleaded facts as true, and draws all inferences in favor of the non-moving party. *Estate of Davis v. Wells Fargo Bank*, 633 F.3d 529, 533 (7th Cir. 2011). In addition, the court construes *pro se* complaints liberally. *Erickson v. Pardus*, 551 U.S. 89, 93 (2007).

In deciding a motion to dismiss, district courts have discretion to consider certain documents outside the pleadings without converting the motion under Rule 12(b)(6) to a motion for summary judgment under Rule 56. *Levenstein v. Salafsky*, 164 F.3d 345, 347 (7th Cir. 1998). In particular, documents submitted with a motion to dismiss may be considered part of the pleadings if they are "referred to in the plaintiff's complaint and are central to his claim." *188 LLC v. Trinity Indus., Inc.*, 300 F.3d 730, 735 (7th Cir. 2002) (internal quotation marks omitted); *see also Brownmark Films, LC v. Comedy Partners*, 682 F.3d 687, 690 (7th Cir. 2012) ("[T]he incorporation-by-reference doctrine provides that if a plaintiff mentions a document in his complaint, the defendant may then submit the document to the court without converting the defendant's 12(b)(6) motion to a motion for summary judgment.").

ANALYSIS

A. Subject Matter Jurisdiction

As an initial matter, plaintiff has made no mention of the Court's basis for jurisdiction, and defendant has likewise not raised the issue. Nevertheless, I address the issue *sua sponte*. *Hay v. Indiana State Bd. of Tax Com. Rs.*, 312 F.3d 876, 879 (7th Cir. 2002) ("[N]ot only may the federal courts police subject matter jurisdiction *sua sponte*, they must."). A complaint must contain "a short and plain statement of the grounds for the court's jurisdiction." Fed. R. Civ. P. 8(a)(1). But a "document filed *pro se* is to be liberally construed and a *pro se* complaint, however inartfully pleaded, must be held to less stringent standards than formal pleadings drafted by lawyers." *Erickson v. Pardus*, 551 U.S. 89, 94 (2007). A court may assume jurisdiction where a *pro se* plaintiff has failed to include a jurisdictional statement if it is otherwise clear from the context the

source from which jurisdiction arises. *Smoot v. Mazda Motors of Amer., Inc.*, 469 F.3d 675, 677 (7th Cir. 2006) (finding amount in controversy requirement met for purposes of diversity jurisdiction based on the severity of the injuries alleged, including medical treatment and permanent injuries related to a jaw injury).

Here, I am satisfied that this Court has diversity jurisdiction pursuant to 28 U.S.C. § 1332. Plaintiff alleges that he is a citizen of Wisconsin and that defendant has its principal place of business in Illinois. It appears defendant is incorporated in Illinois as well. *See Abbott Laboratories v. CVS Pharmacy, Inc.*, 290 F.3d 854, 857, n.2 (7th Cir. 2002). In addition, the amount in controversy requirement is met based on the severity of the injuries alleged by plaintiff, including medical expenses, damages, and pain and suffering related to his alleged permanent vision loss and related symptoms resulting from neurological damage caused by taking Humira.

B. Failure to Warn

With regard to the substance of plaintiff's complaint, defendant argues that plaintiff's failure-to-warn claim must be dismissed because the complaint does not state a plausible ground for relief. Under Wisconsin law, a failure to warn claim or a strict liability claim regarding pharmaceutical labeling requires proof of (1) the existence of a duty to warn; (2) a failure to warn adequately; (3) causation; and (4) actual damages resulting from the injury. *Kessel v. Stansfield Vending, Inc.*, 2006 WI App. 68, ¶ 15, 291 Wis. 2d 504, 714 N.W.2d 206. Manufacturers have a duty to warn consumers of dangers that they know or should know are associated with the proper use of a product. *Strasser v. Transtech Mobile Fleet Service, Inc.*, 2000 WI 87, ¶ 58, 236 Wis. 2d 435, 459, 613 N.W.2d 142, 154.

Generally, the adequacy of a warning presents a factual issue for a jury. *Gracyalny v. Westinghouse Elec. Corp.*, 723 F.2d 1311, 1321 (7th Cir. 1983) (citing *Schuh v. Fox River Tractor Co.*, 63 Wis. 2d 728, 218 N.W.2d 279 (Wis. 1974)); *Kurer v. Parke, Davis & Co.*, 2004 WI App 74, ¶ 24, 272 Wis. 2d 390, 409, 679 N.W.2d 867, 876. The adequacy of a warning depends upon all the circumstances, taking into account factors such as whether the warning is accurate, strong, and clear. *Schuh*, 63 Wis. 2d at 739, 218 N.W.2d at 285. "The clarity of any warnings that were provided is also important; accompanying a warning with misleading representations of safety may serve to render the warning inadequate." *Gracyalny*, 723 F.2d at 1321. Any ambiguity in the language of a warning "is to be construed against the one who chose the words used." *Schuh,* 63 Wis. 2d at 739, 218 N.W.2d 279 at 285 (quotations omitted).

Plaintiff concedes that the Humira label provided warnings regarding the potential association between the use of Humira and certain neurological side effects including demyelinating disease, multiple sclerosis, and vision problems. Defendant asserts that as a result, the express warnings in the Humira label directly contradict the allegations in plaintiff's complaint that the label lacked sufficient warnings. However, while plaintiff does not dispute that the label contained warnings, he contends that the warnings were not adequate. He argues the warnings were misleading in that they omitted material information regarding the severity of the potential side effects and were not clear in explaining that patients without preexisting neurological conditions could also be at risk.

In particular, plaintiff argues that the Humira label's "WARNINGS" section only cautioned of risks of neurologic events for people with preexisting symptoms of a demyelinating disorder. Plaintiff alleges that the label thus "made the drug sound safe" for people without such preexisting

symptoms. (Pl.'s Br. 1, ECF No. 18.) He states he did not have a recent onset of central nervous system demyelination disorder such as multiple sclerosis or symptoms such as numbness or tingling; as a result, he relied on the label in believing that the neurological side effects warned of would not affect him. Defendant contends that the label clearly warned of the risks of neurological conditions in all patients, and in any case, the label was changed in 2005 to warn that rare cases of "new onset" of demyelinating disease have also occurred in patients taking Humira. (Def.'s Reply Br. 4, ECF No. 19.) But plaintiff's reading of the label is also plausible; the warning regarding adverse neurological side effects reasonably appears to be applicable only to patients with preexisting demyelinating disorders or other existing symptoms of central nervous system disorders. At the very least, before 2005, the WARNINGS section of the label was arguably unclear.

Plaintiff also argues that the label inadequately warned about the risks of developing optic neuritis or other permanent optic nerve damage. He claims that while the label warned that Humira users have developed rare cases of disorders affecting the nervous system, it only warned that signs that a person could be experiencing such problems included "problems with your vision." Plaintiff alleges that his vision loss was sudden, and by the time his doctors diagnosed the problem, his vision impairment was permanent. Plaintiff's contention that the label was misleading is plausible. The patient insert warns that a person taking Humira should seek medical attention if they begin to experience certain "rare" side effects such as vision problems. However, the insert and the label fail to alert patients that permanent vision impairment or optic neurosis are potential risks of taking Humira. *See Schuh*, 63 Wis. 2d at 739, 218 N.W.2d at 284-85 ("Implicit in the duty to warn is the duty to warn with a degree of intensity that would cause a reasonable man to exercise for his own safety the caution commensurate with the potential danger." (quotations omitted)).

Plaintiff also alleges that as early as January 2002, other companies manufacturing TNF blocking drugs prescribed for treating rheumatoid arthritis contained labels warning that optic neuritis was a side effect, and therefore, it can be inferred that defendant should have been on notice that optic neuritis and vision loss were risks. (Pl.'s Reply Br., Ex. A at 13, ECF No. 18-1; *Id.,* Ex. B at 9, ECF No. 18-2.) Drug manufacturers "have an affirmative duty to add new warnings to drug labels 'as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.'" *Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 967 (E.D. Wis. 2009) (quoting 21 C.F.R. § 201.80(e)). Moreover, proof of compliance with FDA regulations does not necessarily insulate a defendant from liability; consequently, the fact that Humira's label was FDA-approved at all times relevant here does not in itself defeat plaintiff's claims. *Id.*; *Kurer*, 2004 WI App 74, ¶ 21. If what plaintiff alleges is true, and the risks of developing optic nerve damage associated with repeated use of Humira were known among manufacturers of TNF blockers such as Humira, then a reasonable fact-finder could determine that defendant had a duty to warn of these risks.

Defendant also contends that plaintiff's complaint should be dismissed because the Seventh Circuit Court of Appeals has rejected a similar failure-to-warn claim regarding Humira's label. *Cowley v. Abbott Labs., Inc.*, 476 F. Supp. 2d 1053, 1060-61 (W.D. Wis. 2007). But in *Cowley*, the court was applying North Carolina law and its decision relied on the application of the learned intermediary doctrine. *Id.* Under that doctrine, the court found that the label satisfied the defendant's duty to warn because it provided information regarding the risks and side effects to the patient's physician who testified he had been adequately warned of the adverse effects of the drug.

Id. Wisconsin does not apply the learned intermediary doctrine, and as a result, *Cowley* is also not dispositive here.

In sum, defendant's contention that plaintiff has failed to assert a plausible theory establishing that the warnings were not adequate cannot be sustained. Accepting the complaint's allegations as true, and considering the allegations in light of the label, plaintiff has alleged enough facts to assert a plausible claim for relief. At least at this stage of the proceeding, it is arguable that the label's warning was not adequate.

CONCLUSION

For the reasons set forth herein, plaintiff has stated a plausible claim upon which relief may be granted. Accordingly, defendant's motion to dismiss plaintiff's complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) is **DENIED**. The Clerk will set this matter on the Court's calendar for a Rule 16 scheduling conference.

Dated this 25th day of February, 2013.

s/ William C. Griesbach
William C. Griesbach, Chief Judge
United States District Court